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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,263

Applicant(s)

MATSUMORI, AKIRA

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

The preliminary Amendments filed December 28, 2001 have been entered.

Claims 25-35 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 29 recites the broad

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recitation "viral hepatitis", and the claim also recites "(type A, type B, ... and type TTV)" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 - 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (WO 98/37875, its English translation US Patent 6,277,888 is provided in the IDS received March 27, 2002).

Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating viral hepatitis such as hepatitis B, non-A/non-B hepatitis (See col. 5, line 28-39). Sakai et al. also teaches that the herein claimed compound is useful as treating infectious diseases caused by pathogenic microorganisms (see col. 4, line 27-28; also

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col. 5, lines 41-44). Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating necrosis induced by toxin (See col. 5, line 38).

Sakai et al. does not expressly teach 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating viral myocarditis or ameliorating viral cytotoxicity. Sakai et al. does not expressly teach 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating viral myocarditis caused by orthomyxovirus or picornavirus. Sakai et al. does not expressly teach the hydrochloride salt of herein claimed compound to be useful to treat viral myocarditis and ameliorate viral cytotoxicity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt to treat viral myocarditis or to ameliorate viral cytotoxicity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral myocarditis caused by orthomyxovirus or picornavirus.

One of ordinary skill in the art would have been motivated to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt to treat viral myocarditis or to ameliorate viral cytotoxicity. 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is known to be useful in treating hepatitis B infection (i.e., viral infection caused by hepatitis B virus in the liver). Therefore, employing 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral myocarditis caused by hepatitis B virus, which is viral infection caused by hepatitis B virus in the heart muscle, would have been reasonably expected to be effective since the causative agent is hepatitis B virus and

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the herein claimed compound is effective against such virus. Moreover, treating the infection caused by hepatitis B virus would reasonably expected to ameliorate the viral cytotoxicity caused by the same virus. Furthermore, employ the salt of the active compound or the active compound itself would be obvious as being within the purview of skilled artisan since they are considered therapeutically equivalent.

One of ordinary skill in the art would have been motivated to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral myocarditis caused by orthomyxovirus or picornavirus. Employing the herein claimed compound to combat against infection caused by a RNA virus, such as picornavirus, would have been reasonably expected to be effective since the herein claimed compound is known to treat viral infection caused by RNA viruses such as Hepatitis B and non-A/non-B hepatitis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
October 31, 2002



SREENI PADMANABHAN
PRIMARY EXAMINER

11/2/02